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FORM PTO-1390 (REV. 9-2001)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTORNEY'S DOCKET NUMBER SPER-100A	
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371				U.S. APPLICATION NO. (If known, see 37 CFR 1.5) <b>10/070342</b>	
INTERNATIONAL APPLICATION NO. PCT/US00/23874		INTERNATIONAL FILING DATE 30 August 2000		PRIORITY DATE CLAIMED 01 September 1999	
TITLE OF INVENTION Tool and Method for Cutting Powered by an Electromagnetic (EM) Source					
APPLICANT(S) FOR DO/EO/US SPEARS, Michael Douglas					
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:					
<p>1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.</p> <p>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing under 35 U.S.C. 371.</p> <p>3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</p> <p>4. <input type="checkbox"/> The US has been elected by the expiration of 19 months from the priority date (Article 31).</p> <p>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> has been communicated by the International Bureau.</p> <p style="margin-left: 20px;">c. <input checked="" type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</p> <p>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> is attached hereto.</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</p> <p>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> have been communicated by the International Bureau.</p> <p style="margin-left: 20px;">c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</p> <p style="margin-left: 20px;">d. <input type="checkbox"/> have not been made and will not be made.</p> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).</p> <p>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p> <p><b>Items 11 to 20 below concern document(s) or information included:</b></p> <p>11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input type="checkbox"/> A <b>FIRST</b> preliminary amendment.</p> <p>14. <input type="checkbox"/> A <b>SECOND</b> or <b>SUBSEQUENT</b> preliminary amendment.</p> <p>15. <input type="checkbox"/> A substitute specification.</p> <p>16. <input type="checkbox"/> A change of power of attorney and/or address letter.</p> <p>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825</p> <p>18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</p> <p>20. <input checked="" type="checkbox"/> Other items or information: return receipt postcard</p>					

U.S. APPLICATION NO. <b>10/070342</b> INTERNATIONAL APPLICATION NO. PCT/US00*23874		ATTORNEY'S DOCKET NUMBER SPER-100A			
21. <input checked="" type="checkbox"/> The following fees are submitted: <b>BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):</b> Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO. .... \$1040.00  International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO ..... \$890.00  International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO ..... \$740.00  International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) ..... \$710.00  International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) ..... \$100.00  <b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b>		<b>CALCULATIONS PTO USE ONLY</b>          <table style="width:100%; border: none;"> <tr> <td style="width:50%; border: none;">\$ 740.00</td> <td style="width:50%; border: none;"></td> </tr> </table>		\$ 740.00	
\$ 740.00					
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).		<table style="width:100%; border: none;"> <tr> <td style="width:50%; border: none;">\$ 0.00</td> <td style="width:50%; border: none;"></td> </tr> </table>		\$ 0.00	
\$ 0.00					
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	20 - 20 =	0	x \$18.00		
Independent claims	2 - 3 =	0	x \$84.00		
MULTIPLE DEPENDENT CLAIM(S) (if applicable)		+ \$280.00	\$ 0 00		
<b>TOTAL OF ABOVE CALCULATIONS =</b>			\$ 740.00		
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.			\$ 370.00 +		
<b>SUBTOTAL =</b>			\$ 370.00		
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).			\$ 0.00		
<b>TOTAL NATIONAL FEE =</b>			\$ 370.00		
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +			\$ 0.00		
<b>TOTAL FEES ENCLOSED =</b>			\$ 370.00		
			Amount to be refunded:		
			charged:		
a. <input checked="" type="checkbox"/> A check in the amount of \$ <u>370.00</u> to cover the above fees is enclosed.  b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.  c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>02-0725</u> . A duplicate copy of this sheet is enclosed.  d. <input type="checkbox"/> Fees are to be charged to a credit card. <b>WARNING:</b> Information on this form may become public. <b>Credit card          information should not be included on this form.</b> Provide credit card information and authorization on PTO-2038.					
<b>NOTE:</b> Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.					
SEND ALL CORRESPONDENCE TO:  Jean M. Macheledt Macheledt Bales & Johnson LLP 501 Skysail Lane, Suite B100 Fort Collins, CO 80525-3133  tel: 970-218-6798  *CUSTOMER NUMBER: 28304					
Express Mail number: ET418617179US Date of deposit: <u>28</u> February 2002  I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to Commissioner for Patents, Washington, D.C. 20231  Printed Name: Angie Asmussen 		 SIGNATURE Jean M. Macheledt  NAME <u>33,956</u> REGISTRATION NUMBER			

Rec'd PCT/PTO 28 FEB 2002

**Tool and Method for Cutting Powered by an Electromagnetic (EM) Source****BACKGROUND OF THE INVENTION**

This application claims the benefit of priority under 35 U.S.C. 119(e) and 37 C.F.R. §1.78 to Provisional Patent Application US 60/152,004 filed 01 September 1999.

In general, the present invention relates to medical surgical scalpels that incorporate an oscillating electromagnetic (EM) field source and probe tip to cut biological tissue while, in the case of mammalian tissue, simultaneously cauterizing and coagulating intersecting blood vessels to limit or eliminate blood flow around the tissue site being cut. More particularly, the instant invention relates to a new tool and method for cutting a soft electrically-conductive material such as biological tissue, that operates with radio-frequency (RF) range signals.

The new tool, and associated improved method, comprise a handheld-sized probe housing that encases an impedance matching circuit electrically connected to a conductive cutting tip through a switch-contact area interconnected with the probe housing. Making contact with the switch-contact area allows an electric current to flow through the impedance matching circuit, and due to the proximity of the probe within a region of the material to be cut (since the cutting tip will be in contact with the material being cut), at least one eddy current is induced in the soft electrically-conductive material. The impedance matching circuit may include a capacitive element and an inductive element; and the switch-contact area may contact a spring-engaged conductive-pathway or include the photodetector of an optical switch. The ingenious cutting tool, and associated method, described herein allow a medically-trained and qualified user to cut through a desired area of tissue (any recognized/definable aggregation of cells and intercellular substances) or any other soft electrically-conductive material such as a conductive plastic or phantom material with precision and minimal blood loss, by cauterizing along with the cutting of the material.

Known early-generation surgical tools include the electromagnetic field focusing (EFF) probe and the later-developed electroconvergent cautery (ECC) system, both of which include a system of large, complex external subassemblies; for reference, see FIG. 1 which is a block diagram illustrating the current EFF system setup; and for the ECC system setup, see Patil, A.A., Yamanashi, W.S. "Electroconvergent Cautery" *Neurosurgery*, Vol. 35, No. 4 (October

1944): 785-788. In either case, the handheld probes associated with the EFF or ECC systems (in FIG. 1, EFF probe is labeled **P**) merely include a hot tip for cutting, wiring that extends the length of the probe handle, a vacuum tube attached to an external vacuum source to aid in the removal of vaporized tissue and fluids generated at the hot tip of the probe during operation, and an electrical connector at the other end of the probe handle for connecting to the external, complex impedance matching assembly (such as that represented in FIG. 1 and labeled **IMN**). A separate probe ON/OFF foot pedal, labeled **FP** in FIG. 1, is electrically hardwired to the probe system for use by a surgeon. Unfortunately, the foot pedal switch and the separate probe tuner of the known system are awkward—taking up much-coveted space in an operating room. Furthermore, not only is it difficult for a surgeon to locate, without the benefit of direct visual aids, the foot pedal of these prior devices while concentrating on handling and focusing the probe to cut the necessary area of tissue, but once the foot pedal is located, a surgeon's foot can accidentally fall-off of the pedal— which of course can create very dangerous situations during surgery causing inadvertent injury.

Unlike these known proposed cutting systems, one can readily appreciate the efficient, streamlined design of the handy novel tool and method for cutting of the invention. It is important to note that the new tool preferably has a switch incorporated with a handheld-sized probe housing, as well as impedance matching circuitry encased within the probe housing to help transform load impedance into the characteristic impedance of the input RF power to obtain maximum power transfer (impedance matching) and improve coupling efficiency of the tool network, all of which make the new tool more convenient to a user. Additionally, the tool of the invention operates safely, if properly used as particularly suggested within tested operating parameters, without taking up much-coveted operating room space. Furthermore, in high precision cutting applications such as in neurosurgery and other microsurgical applications, the tool provides a cutting alternative that operates by applying an RF current to mammalian body tissue without causing extremely painful muscle contractions or nerve stimulation as well. Therefore, a cost-efficient, more compact and portable precise cutting tool and associated method for cutting soft electrically-conductive material, such as biological tissue, are needed — preferably to include the ability to cauterize during the process of cutting to minimize blood loss in the case of cutting mammalian tissue. Both the tool and associated method have been designed for simplified, ready operation by trained personnel. As one can appreciate, within the spirit and scope of design goals contemplated hereby, the new tool, method, and associated components and subassemblies can be built using various suitable materials and structures; and a wide variety of materials may be cut using the tool, for a wide variety of applications.

### SUMMARY OF THE INVENTION

It is a primary object of this invention to provide a tool and method for cutting soft electrically-conductive material, such as biological tissue (any definable aggregation of healthy and unhealthy cells and intercellular substances, including fibrous tissue, whether of mammal or plants), phantom tissue, as well as soft polymers, comprising a radio-frequency (RF) source electrically connected to an impedance matching circuit comprising a tuning element electrically connected to an inductive element. The inductive element is electrically connected to a conductive cutting tip through a switch-contact area. The impedance matching circuit is encased by a handheld-sized probe housing and the switch-contact area is interconnected with the housing. The switch-contact area can also be encased within the probe housing, as part of a switch. A further object of the invention is to provide the tool and method for cutting such that, when the probe is positioned in proximity to the soft electrically-conductive material, making contact with the switch-contact area allows an electric current to flow through the impedance matching circuit inducing at least one eddy current in the material within a region of the material to be cut.

Although the advantages of providing the novel, flexible tool and associated method of the invention, as described herein, will be more-fully appreciated in connection with the full specification, certain advantages are listed as follows:

(a) Versatility of operation — The tool can be used for on-site cutting by a trained operator, of a myriad of types of soft materials, including those identified and characterized herein, within which an eddy current can be induced with the aid of an inductive element encased by the probe housing.

(b) Simplicity of design and use — An operator of the tool has at her/his 'fingertips' a means by which a material can be cut, and if the material is mammalian tissue can also be cauterized to minimize blood loss. Not only is a switch incorporated with the probe housing so as to be directly accessible when holding the compact novel probe unit of the invention, but also impedance matching is done utilizing circuitry encased by the probe housing.

(c) Product accuracy and overall cost reduction — Eliminating the need for moving and positioning complex, heavy additional components and assemblies of known systems (such as the large separate, expensive movable solenoid coil - variable capacitor assembly of the EFF system) saves time during operation of the tool and may decrease human error in high precision cutting of materials, leading to a more economically-feasible tool/method.

(d) Design flexibility — Providing electromagnetic (EM) shielding within/around the probe unit decreases EM radiation therefrom allowing the novel tool to be used in spaces with other electronic equipment (such as operating room patient monitoring equipment, or other medical devices used during surgery) with less risk of EM interference and to meet promulgated product safety design guidelines. Further, the small footprint of the tool of the invention allows for use in many locations from an operating room to an assembly plant.

(e) Ready implementation of invention — off the shelf components of a variety of shapes and sizes, modified as needed and incorporated with new structures and RF source and associated equipment, may be utilized in carrying out the features of the invention.

Briefly described, once again, the invention includes a tool for cutting a soft electrically-conductive material, comprising a radio-frequency (RF) source electrically connected to an impedance matching circuit comprising a tuning element electrically connected to an inductive element. The inductive element is electrically connected to a conductive cutting tip through a switch-contact area. The impedance matching circuit is encased by a handheld-sized probe housing and the switch-contact area is interconnected therewith. Further characterized is an associated method for cutting a soft electrically-conductive material using a probe to which a radio-frequency (RF) source is electrically connected, comprising the steps of: providing RF power from the source to an impedance matching circuit electrically connected to a conductive cutting tip through a switch-contact area; and making contact with the switch-contact area to allow an electric current to flow through the impedance matching circuit, for inducing at least one eddy current in the soft electrically-conductive material within a region of the material to be cut.

There are many further distinguishable features of the invention: Many different types of soft electrically-conductive material may be cut, including biological tissue; the inductive element can comprise a step-up transformer (for example, having a secondary to primary winding ratio of 2:1 and a magnetic core) and the tuning element can comprise a capacitor electrically connected to a center-tap of the transformer. The probe housing can be cylindrical in shape and can include an electrically insulative layer and an EM-shielding layer. The switch-contact area can also be encased by the probe housing. A first end of the tip (of many shapes, sizes, and configurations, including straight, curved/twisted, hollow or solid needle-like member of varying cross-sectional shapes) can extend outwardly from the housing through a generally nonconductive sleeve, and a second end portion of the tip can be interconnected to the housing with a release mechanism; the release mechanism may comprise a threaded-section engagable within this sleeve. The RF source can be in electrical communication, by way of

cabling or remote RF signal emission, *etc.*, with the tuning element through a cable and a cable-release assembly.

A novel switch having a nonconductive protuberance extending through an aperture in a switch casing can further be included, the protuberance can have at least one surface in contact with a spring-engaged conductive-pathway whereby a sufficient force directed against the protuberance causes the conductive-pathway to make contact with the switch-contact area allowing an electric current to flow. The conductive-pathway can be an elongated member, a thin plate member, and so on; wherein a stay incorporated with (by way of being integral/molded into or otherwise suitably attached or adhered to) an inner wall of the switch casing supports the member until sufficient force is directed against the protuberance to allow the electric current to flow to the cutting tip. The switch-contact area can comprise a first and second sub-area each atop, respectively, a first and second ledge secured to the switch casing; wherein the switch also has a spring assembly interposed between the conductive-pathway member and an inner surface of the casing. The switch-contact area can comprise a photodetector of an optical switch for completing a circuit.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

For purposes of illustrating the flexibility of design and versatility of the innovative tool and method (including novel additional features), the invention will be more particularly described by referencing the accompanying drawings of embodiments of the invention, in which like numerals designate like parts. The figures have been included to communicate features of the innovative process and system of the invention by way of example, only, and are *in no way* intended to limit the disclosure hereof. Representative dimensions identified in connection with the figures are by way of example, only.

FIG 1 is a block diagram illustrating a known electromagnetic field focusing (EFF) system setup.

FIG. 2 illustrates example features of a preferred tool of the invention shown diagrammatically in block form and labeled 10.

FIGs. 3 and 4 are schematic illustrations of various features, several of which are shown in cross-section and others shown diagrammatically, of a preferred tool of the invention labeled, respectively, 100 and 140.

FIG. 5 is also a schematic illustration of features, a few of which are shown in cross-section, of an alternative tool labeled 40.

FIG. 6 is a sectional view diagrammatically illustrating certain feature details of a preferred switch 110 for a tool of the invention.

FIG. 7 is a circuit model at 185 diagramming matched load,  $Z_L = 51 - j1$  ohms ( $\Omega$ ), from the circuit diagram of a tool of the invention, including a transformer and tuning element (here, a capacitor represented by complex impedance,  $-j\omega c$ ).

FIG 8 is a block diagram illustrating an optic switch system setup labeled 200.

FIG. 9A schematically illustrates a porro prism such as that used in an alternative switch of the invention, to couple a source optical fiber to a detector optical fiber to provide switching capability (based upon detecting a change in light beam intensity) for the optical switch.

FIG. 9B schematically illustrates another means by which an alternative switch of the invention can operate by detecting changes in intensity of a beam of light passing from a source fiber to a detector fiber: The detector optical fiber is bent back in the direction of the source optical fiber, as shown.

FIG. 10 is a flow diagram included for purposes of understanding tool operation and illustrate process feature details associated with tools of the invention shown in other figures.

#### **DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS IN DRAWINGS**

Turning directly to the block diagram of preferred tool 10 of FIG. 2, RF source 35 is comprised of, as shown, signal generator 34 and RF amplifier 30. The electrical connection labeled 36 can comprise coaxial, shielded cabling or other suitable means by which RF power can be supplied to the probe 20 and ultimately to cutting tip 22, such as remote EM emission antenna circuitry. Box 32 illustrates an alternative interconnection with an optical switch control box for use in the event switch 11 is an optical switch.

In principle, soft electrically conductive materials, such as mammalian tissue, plant tissue, soft polymers containing a conductive agent, including soft materials capable of maintaining surface eddy currents and that support a molecular structure having bonds capable of being broken by the temperatures experienced at the cutting tip-material interface, may be cut utilizing a tool of the invention. The probe unit is placed in proximity to an oscillating electromagnetic (EM) field source such that at least one eddy current is induced in the tissue and are made to 'converge' on the tip of the probe. After the cutting tip is touched to the soft material to be cut, the impedance 'mismatch' between the cutting tip and the generator is minimized tending toward a value of zero, resulting in high-current density at the probe tip, causing a small electrical arc to form and 'pinpoint' heating of the soft material to occur (as well as some amount of vaporizing of the soft material) at the point where it is touched without much spread of heat to surrounding soft material. In the case of mammalian tissue, this



heating generally functions to enhance hemostatic capability to cauterize blood vessels in the vicinity of the cutting such that low-blood loss surgery is possible in tissues with relatively small diameter blood vessels (for example, 0.5mm for arteries and 1mm to 2mm for veins). More-particularly medical applications related to use of the tool and method of the invention in connection with mammalian tissue include, among other things, general surgery (tumor, cyst, and polyp removal, vaporization, and resection of internal organs), neurosurgery and other micro-surgery procedures (including cauterizing lesions and blood vessels, vaporization of tumorous tissue, and so on), shrinkage and embolization of aneurysms, removal of atherosclerotic plaque in arteries, and treatment of tissues and organs.

Next, preferred tool 100 in FIG. 3 includes a tip 122 for cutting any of a multitude of soft electrically-conductive materials in which an eddy current can be induced by way of an inductive element such as the coil shown at 112 positioned in proximity with the material. The tip 122 is interconnected with and extending from a preferably generally non-conductive sleeve 124 of a distal end 120 of probe housing 111 which, as illustrated here, is generally cylindrical in shape although housing 111 may be fabricated into any of a number of suitable elongated, hollow shapes of varying cross-sections. The cutting-tip 122 is preferably releasably engaged to the distal end 120 of the probe housing by way of a suitable release mechanism such as a threaded portion 125 engaged within a mated threaded portion (not illustrated for simplicity) of housing 111, a quick-release or quick-lock type mechanism, a press-fit engagement with mechanical interlocking features (not shown), and so on. In electrical communication with conductive tip 122 is a conductive spacer 126 sized to fit snugly and securely, as shown, within molded features of housing 111 or by way of gripping, application of an adhesive, employing an interconnect or interlock mechanism, *etc.* Spacer 126 is electrically connected to switch 110', the details of which are provided in connection with the other figures including FIG. 6.

The switch 110' is conveniently located as a part of the probe unit 100, with a switch-contact area 113' preferably encased by probe housing 111 to complete, when switch-contact area is in a 'closed' position, an electrical pathway from a cable-release assembly 134 to tip 122 that is conveniently encased by housing 111. Note that cable release assembly 134 provides a means by which RF power from an external RF source (35 in FIG. 2) can be releasably connected through electrical contact 132 within housing 111, such that a preselected RF signal may be passed through an impedance matching circuit (outlined at 118 for reference) contemplated herein to comprise a tuning element 130 and an inductive element 112 shown as a coil with a core 116, and along the length "L" of the probe unit 100 out through tip 122 to cut the material/tissue. Once values for elements 130 and 112 are identified according to

established RF circuit matching and tuning principles, with first winding 114 connected to ground, closing switch-contact 113' allows the current to flow.

Established principles of load matching and tuning RF circuits are summarized, here, for reference. The concept of impedance compensation (more commonly termed impedance matching) dictates that RF components are preferably selected for circuits including RF transmission lines such that impedance properties of each device is compatible with the associated transmission system into which the device is incorporated. Properly matched components allow for more efficient power transmission whereas badly 'mismatched' components will result in loss of energy through the RF circuitry. According to circuit theory, maximum power transfer occurs where the load impedance is equal to the complex conjugate of the generator (sometimes referred to as a conjugate match); and in transmission line problems, matching occurs by terminating the transmission line in its characteristic impedance—for example, a transmitter is ordinarily matched to an attached coaxial cable for maximum power transfer. Important parameters when minimizing reflected power and maximizing power transferred in RF transmission circuitry, resulting in impedance matching a source to a load thereof, include the well known parameters: reflected/transmitted power; Standing Wave Ratio (SWR); permeability,  $\mu$ ; transmission line parameters; characteristic impedance,  $Z_0$  (also known as surge impedance); and resonance (at resonance, inductive reactance,  $X_L$ , and capacitive reactance,  $X_C$ , of the circuit effectively cancel each other as they will be equal in magnitude and opposite in phase, or  $180^\circ$  out of phase).

In connection with resonance, the concept of 'tuning' an RF circuit comes into play: Tuning is the adjusting of an RF circuit to reach resonance at a desired operating frequency. A resonant frequency is, thus, that frequency at which a tuned circuit exhibits a sharp change in impedance – an ideal state for obtaining maximum power transfer within the RF circuitry (by way of example,  $f_o = 13.56$  MHz from a 20 Watt amplifier). The probe unit (e.g., 100, 140 of FIGs. 3 and 4) of the invention preferably has component values identified such that probe RF circuitry will be in an impedance matched state while in contact with the soft material which will be cut. For example, human tissue may be impedance matched in connection with a tool of the invention to effectively cut to a depth of 2mm.

Tuned circuits may be classified as tunable or fixed-tuned depending on whether the frequency of the tuned circuits can be varied and narrow-band or wideband depending on the shape of their characteristic (Q) curves. According to whether RLC components are connected in series or in parallel, a tuned circuit is initially referred to as being either series-tuned or parallel-tuned circuits. Fixed-tuned circuits are generally set to operate at a single frequency.

Some nominally fixed-tuned circuits are adjustable, allowing for adjustment of the reactive elements of the tuned circuit over a narrow range – the purpose of which is to compensate for minor variations or imperfections in the circuit elements. The impedance matching circuit illustrated (represented at 118 in FIG. 3) is an example of a two-element series nominally fixed-tuned circuit. Series-tuned circuits are generally useful in applications where it is desired that the device pass a signal of one frequency with minimum attenuation while rejecting other frequencies: there is effectively one resonant frequency for each LC combination.

As shown in greater detail in FIG. 4, the inductive element is preferably a transformer 144 having primary 145 and secondary 147 windings around a core 146 to step up the voltage to a level that the probe unit 140 can utilize to cut the desired soft material (biological tissue, phantom tissue, or soft plastic, for example). The transformer 144 also operates to transform the apparent impedance of the load, here the probe unit 140, into a value matched to the amplifier (at 30 in FIG. 2) supplying power to it. Core 146 is preferably a magnetic core employed for the purpose of increasing inductance (by affecting permeability of the element) as well as coupling efficiency of the probe circuitry. An increase in core permeability of the transformer 144 will increase magnetic flux of the element 144 according to established mathematical relationships, and increasing magnetic flux increases inductance of the inductive element. A variable capacitor such as that represented at 130 can be employed to tune the probe circuitry. Tuning element 130 is center tapped via electrical pathway 148 to secondary winding 147 of inductive element 144 and shown grounded at 137, are both primary winding 145 as well as conductive capture mechanism 133 of cable-release assembly 134 (which may be an off-the-shelf BNC type connector). Furthermore, as designed here, a magnetic core having the capability to be positioned along windings 145, 147 allows for an additional degree of freedom to aid in tuning the circuit as a 'variable inductor'.

By way of example only, one may design the probe circuit to operate with an RF signal resonating at 13.56 MHz for cutting and cauterizing mammalian tissue utilizing a single-layer autotransformer (such as that illustrated at 144 in FIG. 4) having a primary winding (N1) equal to 20 turns and a secondary winding (N2) equal to 40, therefore having a winding ratio of 2:1. Wiring within the probe 140 may, by way of example, comprise 16 gauge wire (AWG)–chosen for its high fusing current rating (approximately 117 amperes). Electrical connection between components can be by way of soldering or other means for causing a solid electrical connection. A silver-mica capacitor may be used for tuning element 130 – these devices are known to be generally stable over a wide operating range of frequencies. Parameters of interest in calculating capacitance of a tuning element (such as that labeled 130 in FIG. 4) for the RF circuitry of the invention to support a signal that resonates at 13.56MHz, include:  $\omega_0$

= frequency of signal in radians/sec;  $L$  = inductance (H);  $C$  = capacitance (farads); which one can readily calculate at:  $C = \sim 7 \text{ pf}$ .

Two types of magnetic cores often used for RF transformers are iron powder cores and ferrite cores. Ferrite cores are useful for higher frequency RF applications in the gigahertz ( $1\text{GHz} = 10^9 \text{ Hz}$ ) range, and iron-powder cores are used in the lower-end of the RF spectrum, with iron powder cores in wide use in RF circuitry. One commonly used iron powder core is made of carbonyl E material. The inductance,  $L$ , of a single-layer iron powder core coil depends on several parameters, including:  $\mu_{\text{eff}}$  = effective permeability of coil;  $N$  = number of turns of the coil;  $r$  = radius of core/coil; and  $l$  = length of core/coil. By way of example only, for a step-up transformer having an iron powder core with the following representative dimensions, one can calculate inductance,  $L = 19.82 \mu\text{H}$  (for purposes of design, one may round to  $20 \mu\text{H}$ ): radius of wire (16 gauge) =  $0.0254''$ ; diameter of iron-powder core =  $250/1000 = 1/4''$ ;  $\mu_{\text{eff}} = 9$ ;  $r$  = radius of core and coil =  $.250/2 + .0254 = 0.150''$ ;  $l$  = length of coil/core =  $1.5''$ ; and  $N=40$ .

Encased within probe housing 111 is a switch-contact area shown generally at 113 as positioned within switch casing 162 and described in greater detail in connection with FIG. 6 along with other features of switch 110. Tip 142 is interconnected in a releasably engaged fashion with, and extending from, generally non-conductive sleeve 124. Tip 142, made of any suitable conductive material cable of withstanding temperatures to which it will be exposed during operating such as titanium alloy, has a press-fit portion 143 engaged through a dielectric thread portion 125 and in electrical contact with conductive spacer 126 – as explained above, sized to fit snugly and securely within molded features of housing 111. Spacer 126 is in electrical communication with the right hand side 181B of switch-contact area 113. Left hand side 181A of switch-contact area 113 is connected to secondary winding 147. Many suitable other replacement structures may function as switch-contacts.

To provide insulation to a user of the live circuitry within probe housing 111, the housing can be fabricated by molding, extrusion, machining, or otherwise, of a generally nonconductive material such as plexiglass or any suitable dielectric, polymer of sufficient structural integrity to provide a housing that suitably contains the features of the invention. Many types of dielectric materials are readily available. Further, to protect circuitry within the probe from getting wet, soiled, and corroded, preferably its housing 111 is designed to be hermetically sealed as necessary. Shown at 141 is an RF-shielding layer embedded within housing 111 made of a conductive foil, for example, such that a user of the probe may be

protected from a good part of stray RF field caused by operation of the RF circuitry within the probe unit 140. In addition, such RF shielding may be required according to promulgated safety medical device design guidelines. It may alternatively be desirable to use a conductive paint applied to an outer surface of the probe housing 111 in a manner that provides RF shielding while at the same time does not create a conductive pathway for leakage current to reside on the outer surface of the housing. In the event probe housing is alternatively machined, extruded or otherwise, of a generally conductive material (metal alloy, for example), a nonconductive coating or layer material such as polyvinylchloride (PVC) tubing is preferably added using suitable adhesive, a heat-seal/shrink wrap, *etc.*, to an outer surface of the metal housing or embedded therein, such that probe unit 140 will not carry a leakage current causing serious injury to a patient or a user of probe 140.

As mentioned in connection with FIG. 2, attached to cable-release assembly 134 is preferably cabling. In the event probe unit 140 (FIG. 4) operates with an RF signal resonating at 13.56 MHz for cutting and cauterizing mammalian tissue, to optimize RF power transfer one can use a quarter-wavelength transmission line, found to be 5.53 m, as a preferred alternative. Taking into account the additional length of a probe unit (length, L, in FIG. 3 which, by way of example only, may be approximately 8 inches) in considering the total length of the RF transmission line of a tool of the invention, one can reduce cabling length to a 5 m cable. By way of example only, a 5 meter shielded coaxial 50 $\Omega$  cable can be connected with assembly 134 to complete a hardwired pathway for RF power from a source (such as that represented at 35 in FIG. 2) to the probe unit (such as those at 100, 140, and 40 respectively labeled in FIGs. 3, 4, and 5). By way of further example, any RF signal generator capable of operating at least within a range of at least 10 MHz to 30 MHz (such as the **Hewlett-Packard** model 3314 with 50 $\Omega$  output), and an associated RF amplifier capable of handling this frequency range, may be employed in a power source used with a cutting tool of the invention.

The probe unit 40 of FIG. 5 illustrates an alternative means by which one can attach a conductive tip (here, labeled 52): an engagement mechanism known as a 'banana jack' having an end 53 with a catch that, upon inserting along directional arrow 58, mates with capture mechanism 55. Capture 55 is shown interconnected to a switch at 50, which is in turn interconnected to inductive element 44, shown here as a transformer with a core 46 to which a tuning element 62 has been center-tapped 48. First winding 49 of the primary coil and a conductive capture mechanism of cable-release assembly 66, are grounded.

The sectional labeled FIG. 6 illustrates suitable structures to function in accordance with the features of a switch 110 of the invention. A protuberance 160 preferably made of a generally nonconductive material extends through an aperture of casing 162. A foot 161 shown integral with protuberance 160 has, as shown but not critical, a donut-shaped area of contact 164 with conductive-pathway member 170. Protuberance 160, and its associated foot 161 (which may merely comprise two or more projections) and its area of contact 164 need only be of a shape and of sufficient structural integrity such that upon the application of force in the direction of arrow 169, area of contact 164 can apply sufficient pressure to member 170 such that conductive areas 171A, 171B make electrical contact with ledges 181A, 181B, respectively, to complete a conductive pathway for current to flow from conductive ledges 181A to 181B through switch 110 completing a circuit through the probe unit (such as those at 100, 140 in FIGs. 3 and 4).

A nonconductive spring assembly 166 comprising a compression dowel 167 and compression spring 165 operate together along with a stay (here comprising the projections labeled 172A, 172B each affixed to an inner wall of casing 162) to maintain positional-spaced relationship between conductive-pathway member 170 and ledges 181A, 181B until sufficient force is applied along arrow 169 to protuberance 160 to make contact between 171A, 171B and 181A, 181B, respectively. The spring assembly operates to apply counter pressure against an undersurface of conductive-pathway member 170, with stay components 172A, 172B configured with a shallow lip to aid in providing balance and support to the periphery of member 170 as well as guide areas 171A, 171B as they move toward ledge members 181A, 181B. The particular shape of ledge members 181A, 181B is not critical, but only that prior to contact with a conductive-pathway member (such as that at 170) the two members are electrically isolated and upon contact, provide a pathway for RF current to flow from an inductive element (*e.g.*, 144) to a tip (*e.g.*, 142). As one can appreciate, many different generally nonconductive polymers and conductive metals/metal alloys (including stainless steel) exist that are readily molded, thermo-formed (in the case of polymers), soldered, micro-machined, extruded, and otherwise fabricated, configured, and assembled according to well known techniques to produce structures according to the invention.

In FIG. 7 a diagram of the matched load,  $Z_L = 51 - j1$  ohms ( $\Omega$ ) is shown at 185 as it has been modeled from a circuit diagram 180 of a tool comprising a probe unit of the invention (such as any of those at 40, 100, and 140). A transformer with core represented at 182 and tuning element 183 (here, a capacitor represented by complex impedance,  $-j\omega c$ ) have been diagramed along with representative load/resistance elements labeled  $R\omega_1$ ,  $R\omega_2$ , and  $R_s$ .

FIG 8 is a block diagram illustrating an optic switch system setup labeled 200 including components such as those found in known optic switch devices. By way of reference, a photodetector is a device that senses the light pulses in an optical fiber and converts them into electrical pulses; photodetectors use the principle of photoconductivity, which is exhibited in certain materials that change their electrical conductivity when exposed to light. At 210 is an alternative switch that may readily be incorporated into a probe of a tool of the invention to replace switch mechanisms labeled 110', 110, and that represented by phantom box 50 in the probe units of FIGs. 3, 4, and 5, respectively. Here, a light emitting diode (LED) operates as the light source. The control box illustrated in FIG. 2 at 32 represents the source and detector fibers, circuitry necessary to provide constant voltage and current for the LED source, as well as detector/amplifier circuitry having an output that is interfaced with the selection of logic gates that also control the operation of the RF generator.

FIG. 9A schematically illustrates a porro prism 230 such as that used in an alternative switch of the invention (identified by box 210 in FIG. 8) to couple a source optical fiber to a detector optical fiber to provide switching capability (based upon detecting a change in light beam intensity) for the optical switch. This porro prism can be fixed within a spring-loaded button (mounted to a piece of clear, nonconductive material such as plexiglass), positioned across two optical fibers. Preferably the optical switch-contact area fits within the probe housing.

FIG. 9B schematically illustrates another means by which an alternative switch of the invention (identified by box 210 in FIG. 8) can operate by detecting changes in intensity of a beam of light 236 passing from a source fiber 232 to a detector fiber 234: The detector optical fiber is bent back in the direction of the source optical fiber, as shown.

FIG. 10 is a flow diagram of process feature details associated with the tools represented in the prior figures. A method for cutting soft materials using a probe to which an RF source is electrically connected is diagramed and labeled 300. RF power is provided from an RF source to an impedance matching circuit electrically connected to a cutting tip through a switch-contact area interconnected with a probe housing (box 310). As noted by call-out 311, and critical to the invention, the impedance matching circuit is encased by the probe housing. Next, to connect the RF source to a probe unit of the invention, one can engage a cable to a cable-release assembly (box 312). Further, to electrically connect the cutting tip with the switch-contact area (box 314), one can engage the tip (via suitable release mechanism) to a distal end of the probe housing. Two alternative steps are depicted (boxes

317A, 317B) in connection with the step labeled 316 for making contact with the switch-contact area (preferably also encased by the probe housing) allowing current to flow through the impedance matching circuit: Directing sufficient force (box 317A) against a protuberance such that a conductive-pathway makes contact with a switch-contact area such as is contemplated by switches 110' and 110 (FIGs. 3 and 4); and directing light waves (box 317B) through one or more optical fiber (source and detector fibers) as is contemplated by the optical switch identified at 210 in FIG. 8. One can appreciate that many different alternative switch structures and associated switch-contact mechanisms are contemplated hereby. Next, a user can position the probe unit in proximity to the soft material, thus inducing at least one eddy current therein within a region to be cut (see box 319). The soft material can then be cut, cauterized, or otherwise operated upon in accordance with principles of the invention (box 320) as contemplated by this disclosure.

While certain representative embodiments and details have been shown merely for the purpose of illustration and those skilled in the art will readily appreciate that various modifications may be made without departing from the novel teachings or scope of this invention. Accordingly, all such modifications are intended to be included within the scope of this invention as defined in the following claims. Although the commonly employed preamble phrase "comprising the steps of" may be used herein, or hereafter, in a method claim, the Applicants *in no way* intends to invoke 35 U.S.C. section 112 ¶6. Furthermore, in any claim filed herewith or that is filed hereafter, any means-plus-function clauses used, or later found to be present, are intended to cover the structures described herein as performing the recited function and not only structural equivalents but *also* equivalent structures.



What is claimed is:

1. A tool for cutting a soft electrically-conductive material, comprising:  
a radio-frequency (RF) source electrically connected to an impedance matching circuit comprising a tuning element electrically connected to an inductive element; and  
said inductive element electrically connected to a conductive cutting tip through a switch-contact area;  
whereby said impedance matching circuit is encased by a handheld-sized probe housing, and said switch-contact area is interconnected with said housing.
2. The tool of Claim 1 wherein: the soft electrically-conductive material is selected from the group consisting of biological tissue, phantom tissue, and polymers; said inductive element comprises a transformer for inducing at least one eddy current in the electrically conductive material within a region of the material to be cut; said probe housing comprises an electrically insulative layer; said cutting tip is releasably engagable to said probe housing; said RF source comprises an RF signal generator and an amplifier; and said switch-contact area is encased by said probe housing.
3. The tool of Claim 2 wherein said probe housing is generally cylindrical in shape and made of metal, said insulative layer comprises a dielectric coating thereon; said tuning element comprises a capacitor; a first end of said tip extends outwardly from said housing; and a second end portion of said tip is so engaged with a release mechanism that comprises a catch for engagement within a distal end of said probe housing.
4. The tool of Claim 2 wherein: said transformer is a step-up transformer having a primary winding a first winding of which is connected to a ground; said tuning element comprises a capacitor electrically connected to a center-tap of said transformer; a first end of said tip extends outwardly from said housing through a generally nonconductive sleeve; and a second end portion of said tip is so engaged with a release mechanism.
5. The tool of Claim 4 wherein said insulative layer comprises a tubular polymeric shell; said probe housing further comprises an EM-shielding layer adhered to an inner wall of said shell; said release mechanism comprises a threaded-section engagable within said generally nonconductive sleeve; and said switch-contact area is of an optical switch.

6. The tool of Claim 4 wherein said RF source is in electrical communication with said capacitor through a cable and a cable-release assembly; said step-up transformer has a secondary to primary winding ratio of 2:1 and further comprises a magnetic core; and said release mechanism is encased within said probe housing.

7. The tool of Claim 1 wherein said switch-contact area is of a switch comprising a nonconductive protuberance extending through an aperture in a casing for said switch, said protuberance having at least one surface in contact with a spring-engaged conductive-pathway; whereby a sufficient force directed against said protuberance causes said conductive-pathway to make contact with said switch-contact area allowing an electric current to flow.

8. The tool of Claim 7 wherein: said RF source is in electrical communication with said tuning element through a cable and a cable-release assembly; said conductive-pathway comprises an elongated member; a stay incorporated with an inner wall of said switch casing supports said elongated member until said sufficient force is directed against said protuberance allowing said electric current to flow to said tip.

9. The tool of Claim 8 wherein: said stay comprises a first and second projection against which said elongated member abuts, said projections being affixed to said inner wall in proximity to said switch-contact area; a second end portion of said tip is releasably interconnected to a distal end of said probe housing such that, upon said interconnection, said tip is in electrical communication with said switch-contact area.

10. The tool of Claim 7 wherein said surface of said protuberance is that of a foot in contact with said spring-engaged conductive-pathway; said conductive-pathway comprises a thin plate member; and said switch-contact area comprises a first and second sub-area each atop, respectively, a first and second ledge secured to said switch casing; and said switch further comprises a spring assembly interposed between said plate member and an inner surface of said casing.

11. The tool of Claim 10 wherein: said inductive element comprises a transformer to which said first sub-area is electrically connected; a first end of said tip extends outwardly from said housing; a second end portion of said tip is releasably engaged to a distal end of said probe housing; such that, upon said interconnection, said tip is in electrical communication with said second sub-area.

12. The tool of Claim 1 wherein: said inductive element comprises a step-up transformer having a primary and secondary winding around a core selected from the group consisting of iron powder cores and ferrite cores, and said tuning element comprises a capacitor electrically connected to a center-tap of said transformer; and further comprising a switch electrically connected between said secondary winding and said tip such that making electrical contact of a conductive-pathway of said switch with said switch-contact area allows an electrical current to flow to said tip.

13. The tool of Claim 12 wherein: said RF source operates at least over a frequency range of 10 to 30 MHz; said probe housing is generally cylindrical in shape and comprises an electrically insulative layer and an EM-shielding layer; a first end of said tip extends outwardly from said housing; and a second end portion of said tip is interconnected with a release mechanism to a distal end of said housing.

14. A method for cutting a soft electrically-conductive material using a probe to which a radio-frequency (RF) source is electrically connected, comprising the steps of:

providing RF power from the source to an impedance matching circuit electrically connected to a conductive cutting tip through a switch-contact area, said circuit being encased by a handheld-sized housing for the probe, said switch-contact area interconnected with said housing; and

making contact with said switch-contact area to allow an electric current to flow through said impedance matching circuit.

15. The method of Claim 14 wherein said current is flowing through an inductive element of said impedance matching circuit comprising primary and secondary windings around a core; and further comprising the steps of positioning the probe in proximity to the electrically-conductive material and inducing at least one eddy current in the soft electrically-conductive material within a region of the material to be cut.

16. The method of Claim 15 wherein: the soft electrically-conductive material is selected from the group consisting of biological tissue, phantom tissue, and polymers; said step of providing RF power further comprises providing said power through a cable electrically connected to said tuning circuit; and said step of making contact further comprises allowing said electric current to flow through said tip for the cutting, wherein said switch-contact area is encased within said probe housing.

17. The method of Claim 14 wherein said step of making contact further comprises directing a sufficient force against a non-conductive switch-protuberance having at least one surface in contact with a spring-engaged conductive pathway within a switch casing, such that said conductive-pathway makes contact with said switch-contact area.

18. The method of Claim 17 wherein said step of directing said force further comprises compressing a spring assembly interposed between said conductive-pathway and an inner surface of said switch casing; and

further comprising the steps of, first, engaging a cable to a cable-release assembly to connect the RF source; and releasably engaging a second end portion of said tip to a distal end of said probe housing to electrically connect said tip with said switch-contact area.

19. The method of Claim 14 wherein the soft electrically-conductive material is selected from the group consisting of biological tissue, phantom tissue, and plastic; said electric current flowing through said impedance matching circuit comprises allowing said current to flow through a tuning element electrically connected to an inductive element; and said step of making contact further comprises directing light waves through an optical fiber to said switch-contact area comprising a photodetector.

20. The method of Claim 19 wherein said step of making contact further comprises allowing said electric current to flow through said tip, extending outwardly from said probe housing, and into the material for the cutting; and further comprising the steps of positioning the probe in proximity to the electrically-conductive material and inducing at least one eddy current in the soft electrically-conductive material within a region of the material to be cut.

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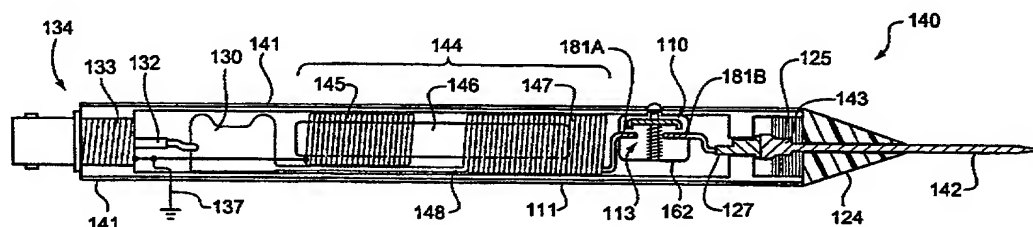
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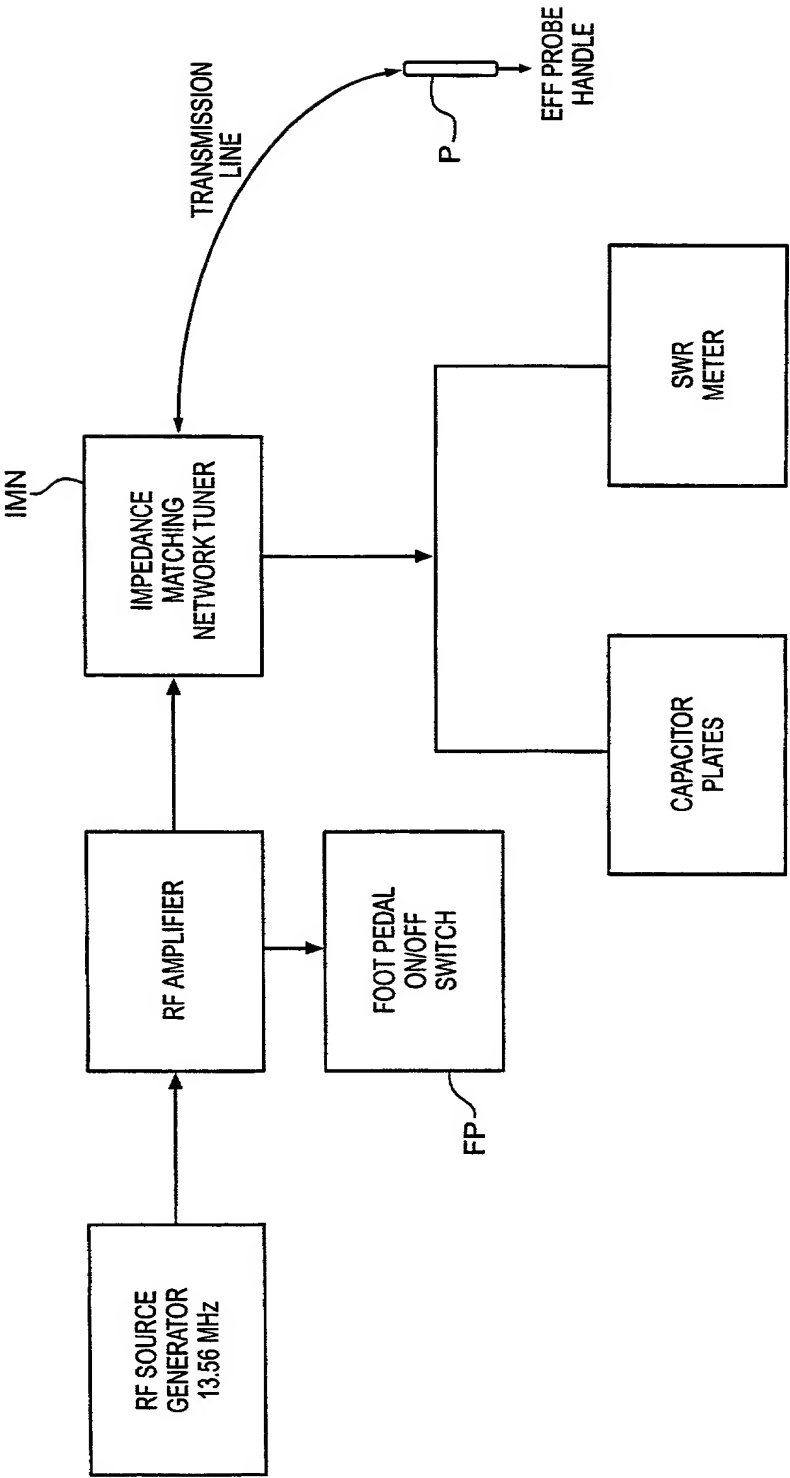
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(54) Title: TOOL AND METHOD FOR CUTTING POWERED BY AN ELECTROMAGNETIC (EM) SOURCE



(57) Abstract: A tool (100) for cutting a soft electrically-conductive material, including an RF source (35) connected to an impedance matching circuit (118) which includes a tuning element (130) connected to an inductive element (112) and which in turn is connected to a conductive cutting tip (122) through a switch-contact area (110). The impedance matching circuit and the switch-contact area are encased by a handheld-sized probe housing (111). Also disclosed is a method for using the tool including providing RF power from the source to an impedance matching circuit connected to a conductive cutting tip through a switch-contact area; making contact with the switch-contact area to allow electric current to flow; and positioning the probe in proximity to the soft material such that at least one eddy current is induced within a region of the material to be cut.

WO 01/15617 A1



**FIG. 1**  
PRIOR ART

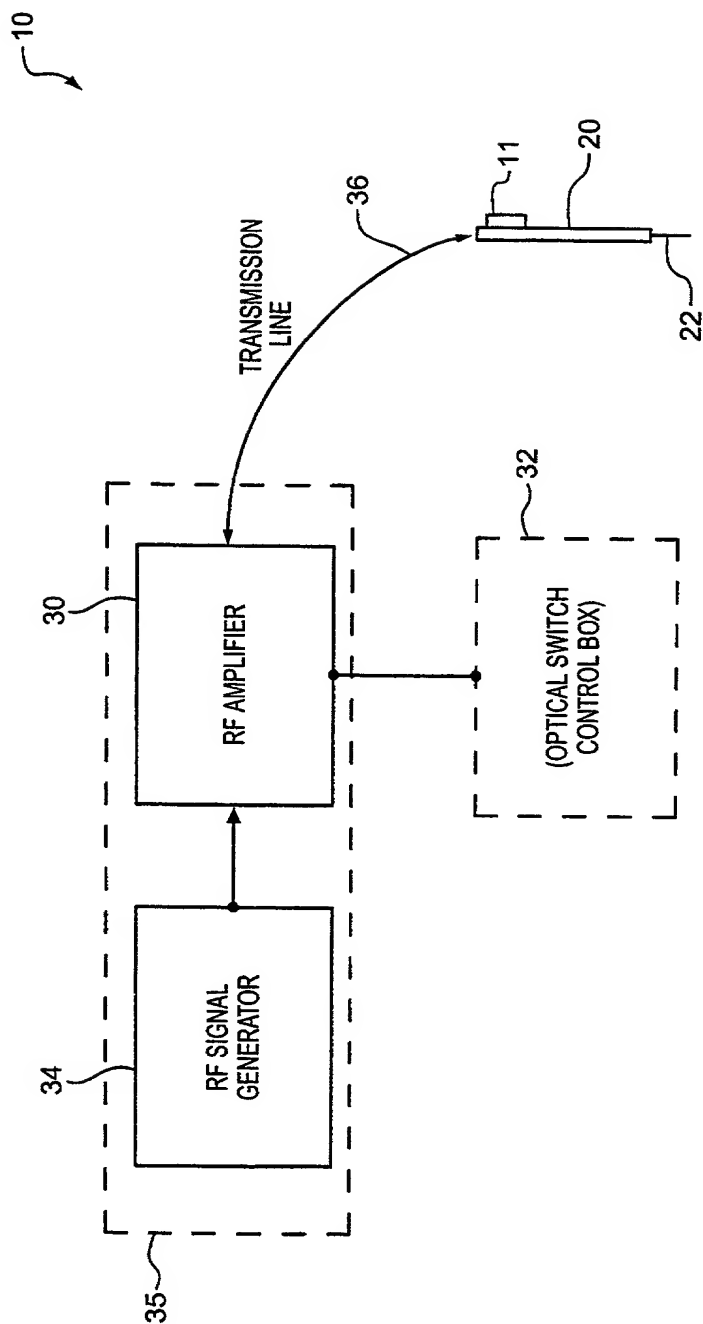


FIG. 2

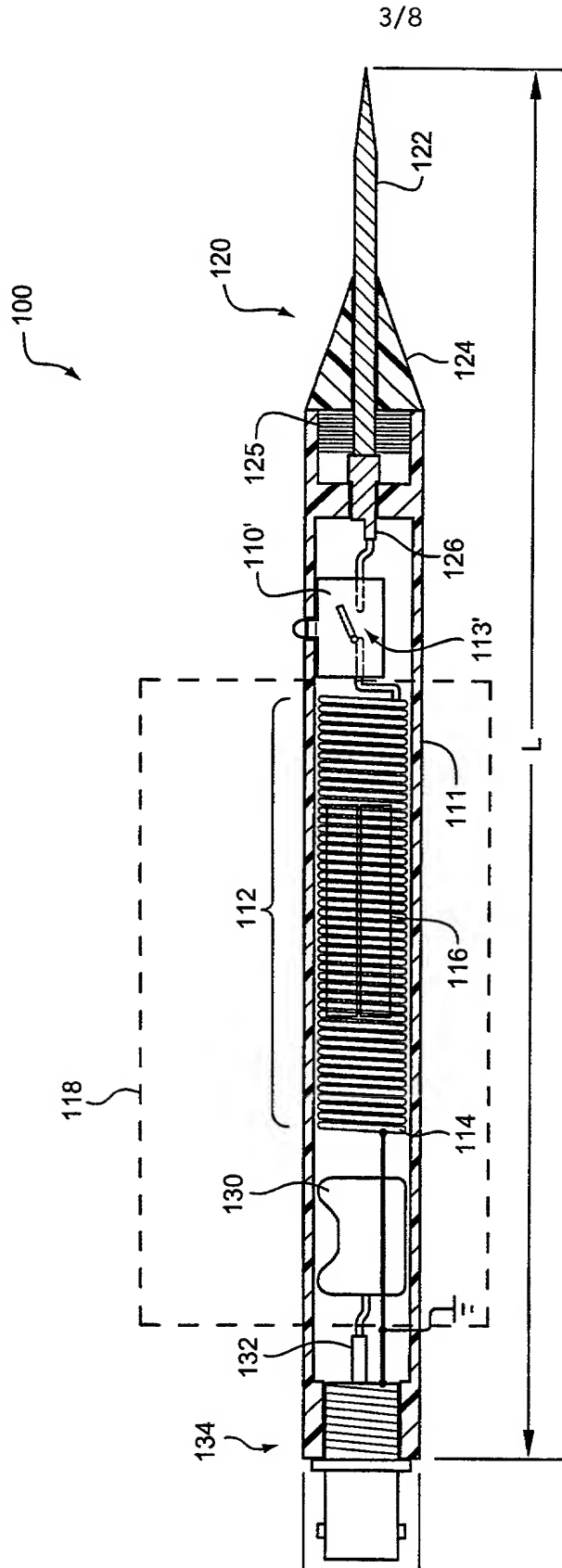


FIG. 3



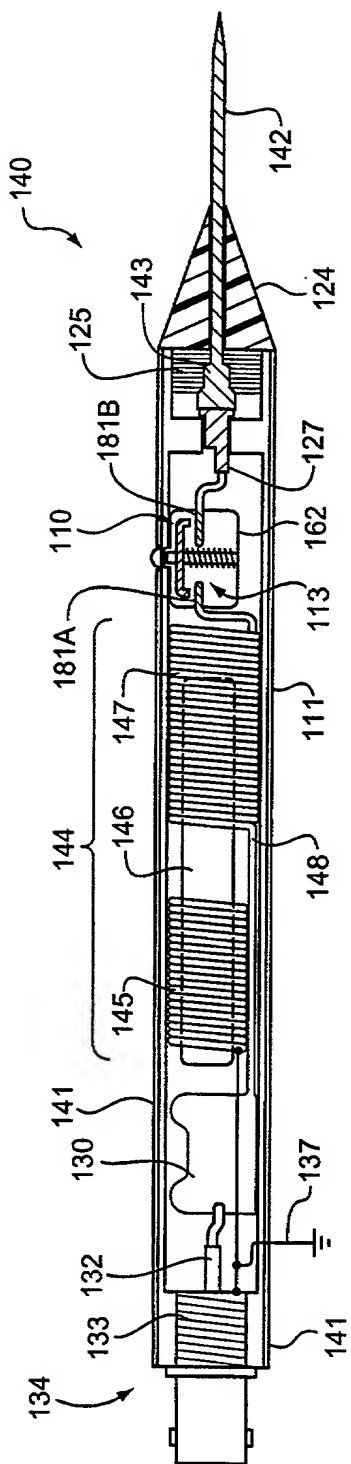


FIG. 4

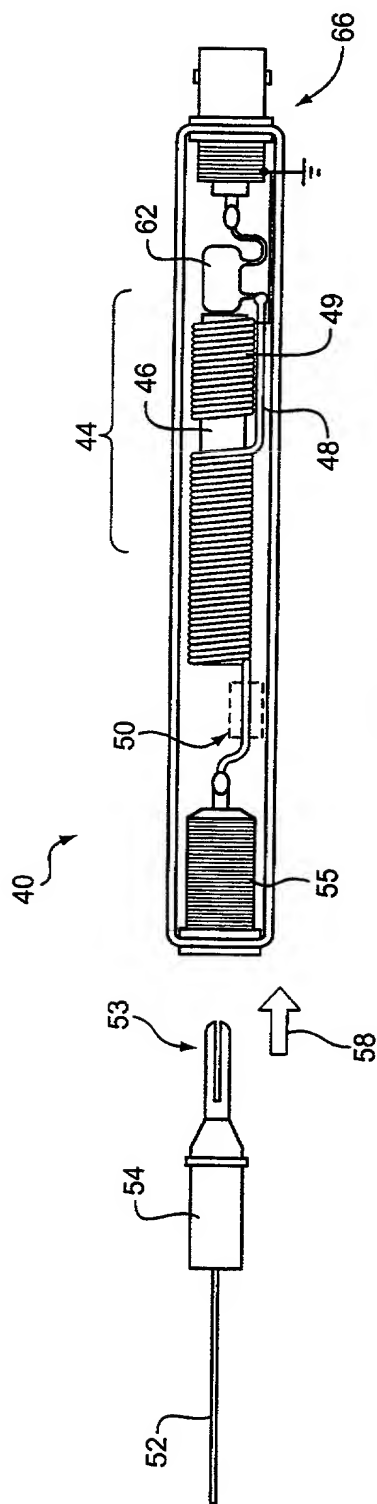


FIG. 5

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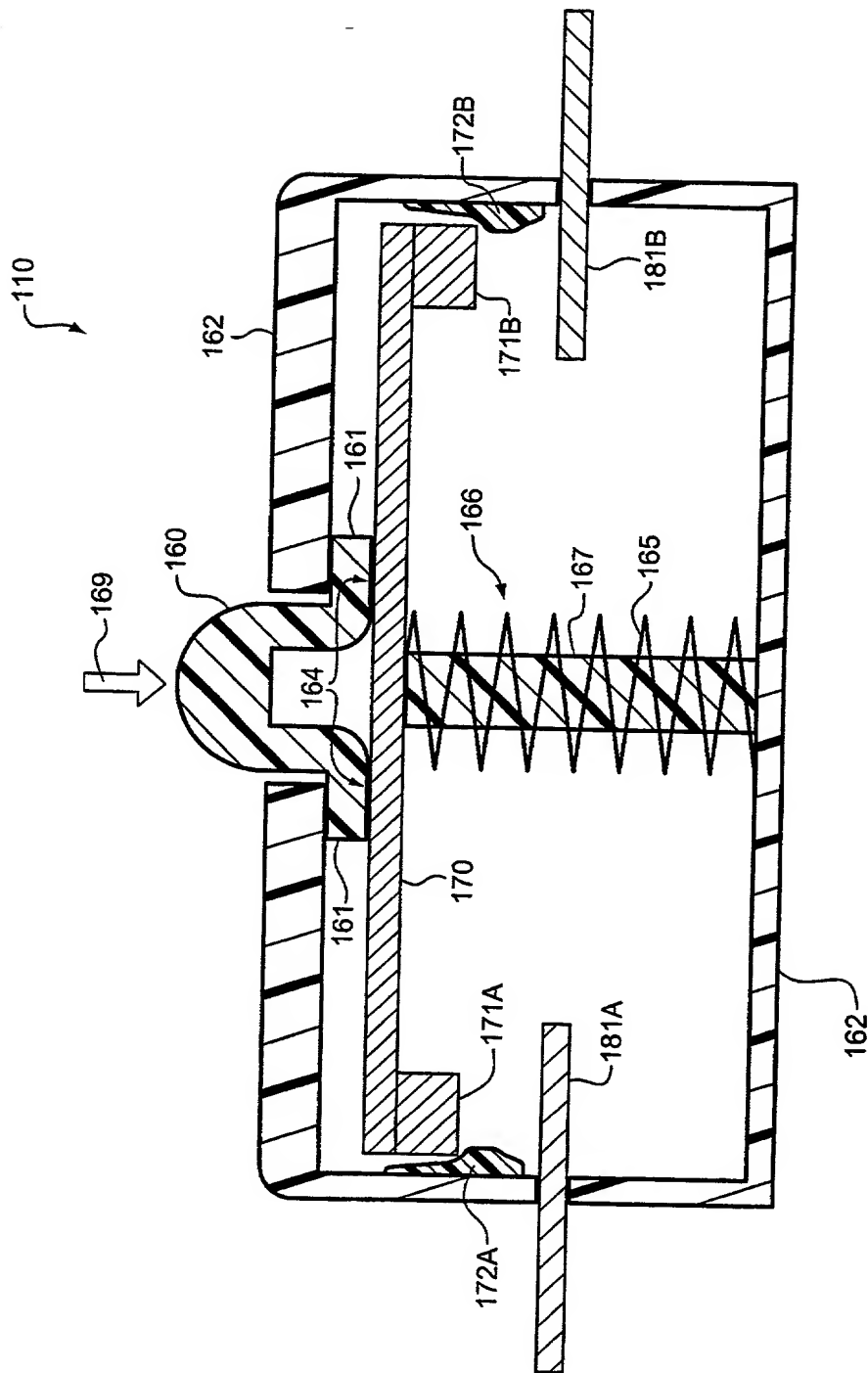
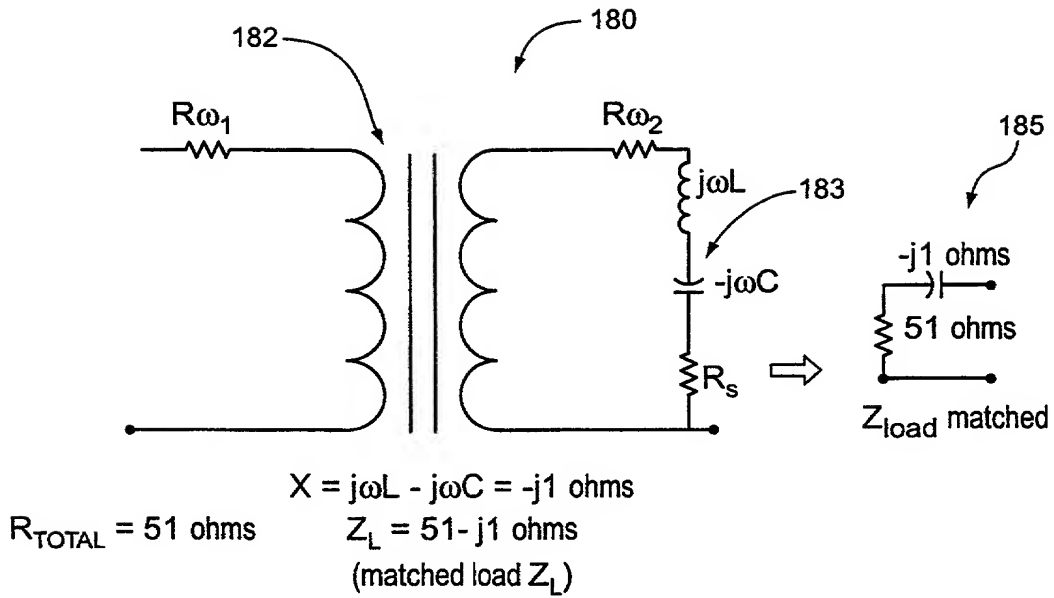
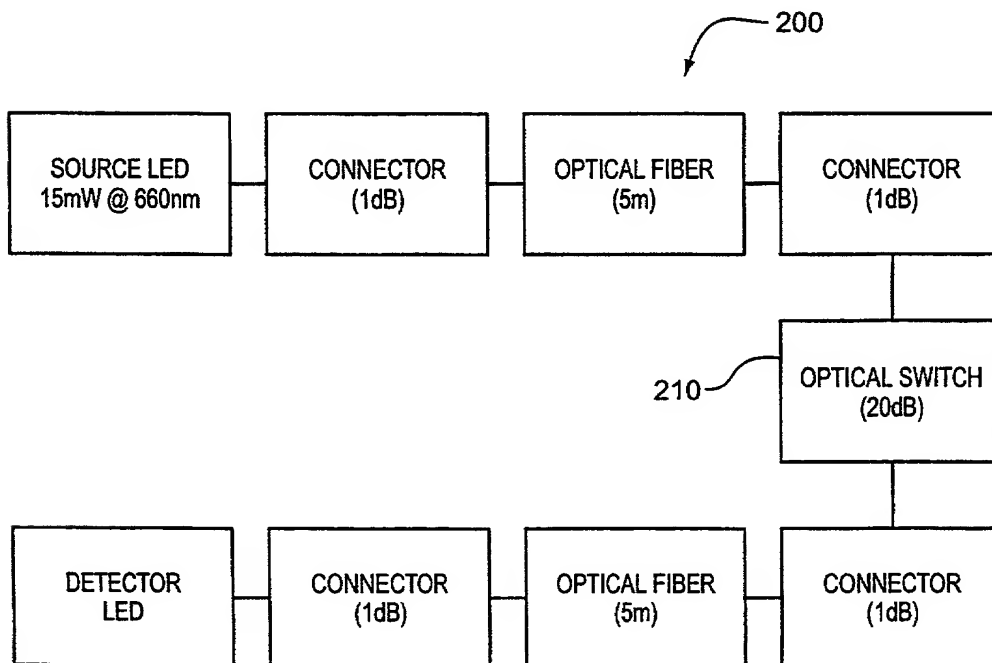


FIG. 6

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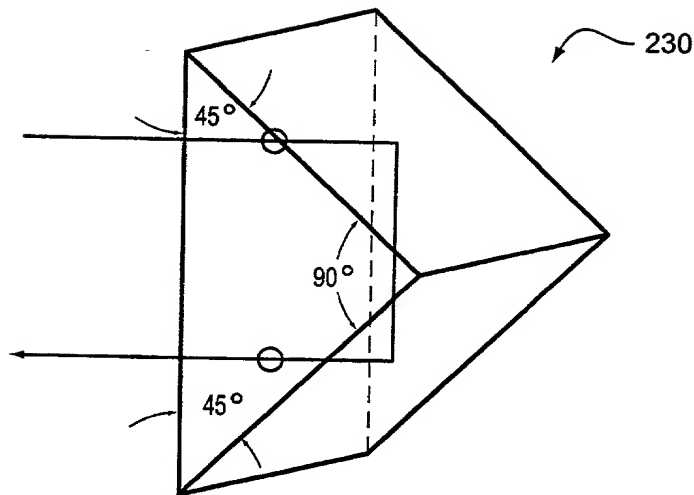


**FIG. 7**

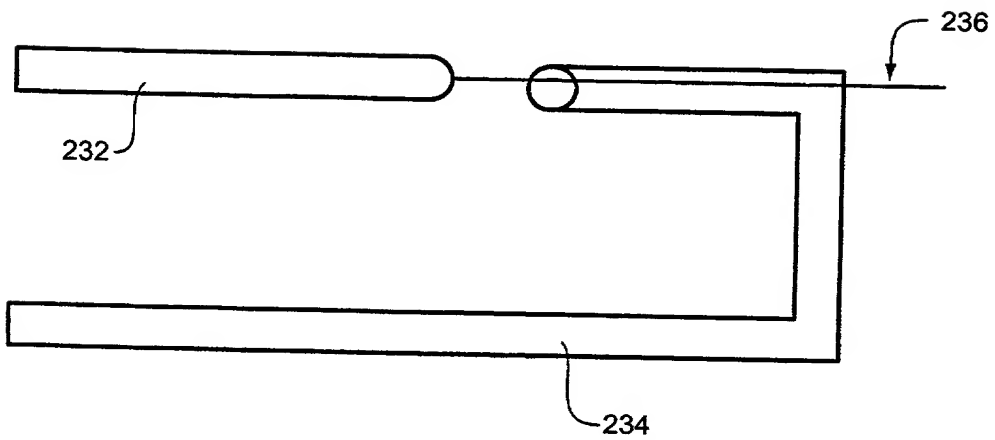


**FIG. 8**

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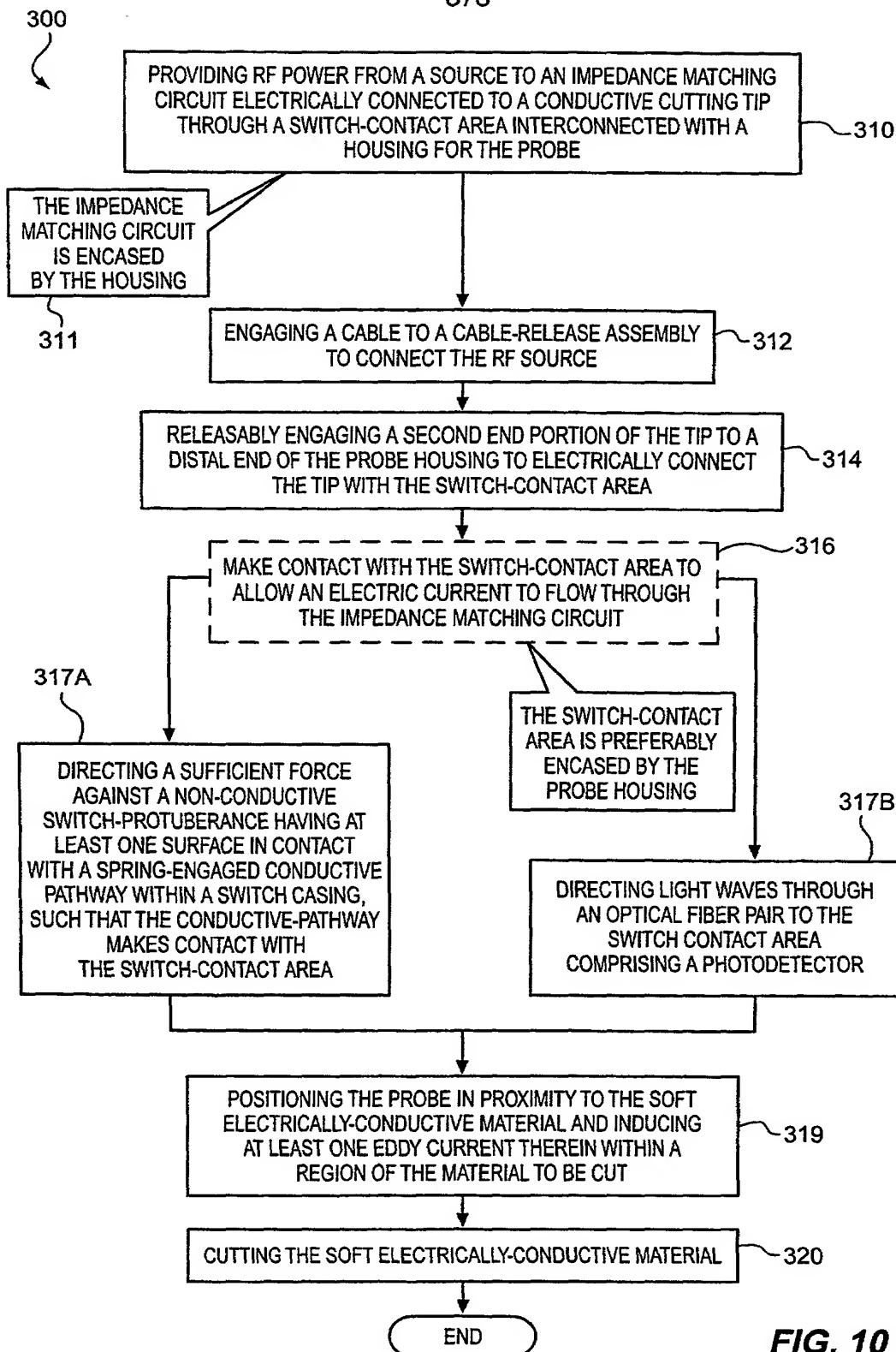


**FIG. 9A**



**FIG. 9B**

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## DECLARATION FOR PATENT APPLICATION AND APPOINTMENT OF ATTORNEY

As a below-named inventor, I hereby declare that my residence, post office address and citizenship are as stated below next to my name; I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention (Design, if applicable) entitled :

**Tool and Method for Cutting Powered by an Electromagnetic (EM) Source.**

the specification of which (check one):

- ☒ is attached hereto.  
☐ was filed on \_\_\_\_\_, as Application Serial No. \_\_\_\_\_, and was amended on \_\_\_\_\_ (if applicable).  
☐ was filed on \_\_\_\_\_, as International Application (PCT) No. \_\_\_\_\_, and was amended on \_\_\_\_\_ (if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above. I acknowledge the duty to disclose information which is material to the examination of this application in accordance with *Title 37, Code of Federal Regulations, § 1.56(a)*. I hereby claim foreign priority benefits under *Title 35, United States Code § 119* of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which the priority is claimed.

## PRIOR FOREIGN APPLICATION(S)

NUMBER	COUNTRY	DAY/MONTH/YEAR FILED	PRIORITY CLAIMED
PCT/US00/23874	UNITED STATES	AUGUST 30, 2000	<u>X</u> Yes

I hereby claim the benefit under *Title 35, United States Code, § 120* of any United States application(s) or PCT international application(s) designating The United States of America listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of *Title 35, United States Code, § 112*, I acknowledge the duty to disclose material information as defined in *Title 37, Code of Federal Regulations, § 1.56(a)* which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

APPLICATION NUMBER	FILING DATE	STATUS (Patented, Pending or Abandoned)
60/152,004	September 1, 1999	Pending (Provisional Application)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine, or imprisonment, or both, under *Section 1001 of Title 18 of the United States Code*, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

**POWER OF ATTORNEY:** I (We) hereby appoint as my (our) attorneys, with full powers of substitution and revocation, to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

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